NOV 1 7 2009

Section 5:

510(k) Summary

(Revision 10/14/2009)

K092374

510(K) SUMMARY

OIS EYESCAN PORTABLE MODULAR IMAGING SYSTEM

510(k) Number K092374

Applicant's Name: Ophthalmic Imaging Systems
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Date Prepared: August 3, 2009 (Revised 10/14/2009)

Trade Name: OIS EyeScan Portable Modular Imaging System

Classification Name: CFR Classification section 886.1120 (Product code HKI)
CFR Classification section 886.1850 (Product code HJO)
CFR Classification section 892.2020 (Product code NFG)

Classification: Class II Medical Device

Predicate Device: The OIS EyeScan Portable Modular Imaging System is substantially equivalent to a combination of the following predicate devices:

Topcon TRC-50EX and TRC-50IX (K041367), manufactured by TOPCON Corp. Topcon TRC devices are ophthalmic camera systems intended to photograph the eye's fundus, similar to the OIS EyeScan device with the Retina Module or Fluorescein Angiography Module. To the best of our understanding, the TRC-50EX received market clearance as an addition or a modification to the 510(k) clearance of the TRC-NW200 device, K041367.

WinStation Digital Imaging System (K913929) manufactured by Ophthalmic Imaging Systems is used in conjunction with ophthalmic fundus cameras to take images of the eye, similar to the OIS EyeScan device using the Retina Module or Fluorescein Angiography Module.

IRI Integrated Retinal Imager (K062295) manufactured by Medivision Medical Imaging is intended to photograph the eye's fundus similar to the OIS EyeScan device using the Retina Module or Fluorescein Angiography Module.

BX900 manufactured by Haag Streit is a slit-lamp biomicroscope with viewing and illumination optical systems, similar to the OIS EyeScan device with the Slit Module, Red Reflex Module or Topical Fluorescein Module. To the best of our understanding, the BX900 received market clearance as an addition or a modification to the 510(k) clearance of the BC900 device K982057.

Tearscope Plus (K973064) manufactured by Keeler is a device for specular observation of the tear film, similar to the OIS EyeScan device with the Tear Film Module.

Device Description: OIS EyeScan is a portable, modular imaging device, which is designed to perform retinal imaging (including color, FA, FAF, Red-free) and corneal imaging (including tear film analysis, corneal fluorescences, slit).

OIS EyeScan Portable Modular Imaging System, consistent with the predicate imaging devices previously listed, uses light photography to obtain clinical information. OIS EyeScan captures images using light sources (LEDs of different colors), functionally optimized lenses and filters, and digital camera sensors. OIS EyeScan uses OIS WinStation software for image capture, review and analysis. The device comprises a base unit, and interchangeable imaging modules and optional chin rest. Images may be stored on industry standard storage media.

Intended Use / Indication for Use: The OIS EyeScan Portable Modular Imaging System is a portable monocular camera intended for imaging of both the posterior segment (including structures of the retina, vitreous and choroid) and anterior segment (including structures of the orbit, lids, cornea, iris and lens) of the eye. The device is suitable for documentation of findings in a clinical setting.

Performance Standards: None. There are no mandatory performance standards for this type of device.

Test Data: The OIS EyeScan Portable Modular Imaging System has been subjected to extensive performance testing and validation before release. Final testing of the OIS EyeScan included various performance tests and software validation tests, designed to ensure that the device met all its functional specifications. EMC and safety tests currently underway will ensure the device complies with industry and safety standards. The device does now or will comply with these industry and safety standards prior to commencing marketing of the device. See Section 9 for statement and declaration of conformity.

Substantial Equivalence: The OIS EyeScan Portable Modular Imaging System is similar to currently legally marketed ophthalmic imaging systems intended for posterior segment and anterior segment imaging applications. Similar to other predicate devices, the operating modes of the device include color, FA, FAF, red-free, ICG angiography, autofluorescence, tear film analysis, corneal fluorescences, slit. The device uses LEDs, similar to other predicate devices, as a safe low voltage light source instead of halogen and xenon lamps. Optical specifications are similar to those of predicate devices. Image processing and storage capabilities are similar to those of predicate devices. All of the above features are similar to these features in the predicate devices.

Conclusions: The conclusions drawn from the above Performance Testing and comparison to predicate devices is that OIS EyeScan Portable Modular Imaging System is substantially equivalent in safety and effectiveness to the predicate devices listed above.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
10903 New Hampshire Avenue
Document Mail Center - WO66-G609
Silver Spring, MD 20993-0002

Ophthalmic Imaging Systems (OIS)
c/o Ms. Andrea Ambrose
Quality Manager
221 Lathrop Way, Suite I
Sacramento, CA 95815

NOV 17 2009

Re: K092374
Trade Name: OIS EyeScan Portable Modular Imaging System
Regulation Number: 21 CFR 886.1120
Regulation Name: Ophthalmic camera
Regulatory Class: Class II
Product Code: HKI, HJO, NFG
Dated: October 14, 2009
Received: October 15, 2009

Dear Ms. Ambrose:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/cdrh/mdr/ for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Kevin Alexander for

Malvina B. Eydelman, M.D.
Director
Division of Ophthalmic, Neurological,
and Ear, Nose and Throat Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

INDICATIONS FOR USE

510(k) Number (if known): K092374

Device Name: OIS EyeScan Portable Modular Imaging System

Indications for Use:

The OIS EyeScan Portable Modular Imaging System is a portable monocular camera intended for imaging of both the posterior segment (including structures of the retina, vitreous and choroid) and anterior segment (including structures of the orbit, lids, cornea, iris and lens) of the eye. The device is suitable for documentation of findings in a clinical setting.

Prescription Use √ (Per 21 C.F.R. 801 Subpart D) OR Over-The-Counter Use___ (Optional Format Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

11/09/09

(Division Sign-Off)
Division of Ophthalmic, Neurological and Ear, Nose and Throat Devices

510(k) Number K092374